Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State
Department of Health
An Equal Opportunity Employer

Vaccine E-Letter # 262.5
12/12/2007
URGENT
PLEASE READ AND ACT ON IMMEDIATELY

www.statehealth.in.gov/programs/immunization.htm

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Hib Vaccine Voluntary Recall

As a precautionary measure, Merck & Co., Inc. ("Merck") has initiated a voluntary recall in the United States for ten lots of PedvaxHIB [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and two lots of COMVAX [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine].

No other lots of PedvaxHIB® or COMVAX® and no other Merck products are affected by this recall.

We are including a copy of the notification letter from Merck along with the Q&A document that CDC has provided to us to share with our vaccine providers. This information will explain how to prepare recalled vaccines for return shipment and the reasons for the recall.

Do not give the vaccines associated with the lot numbers listed in the table in the following letter to anyone. The vaccine itself is still effective, so anyone who has already received a dose of these vaccines will not need to be revaccinated. VFC providers should contact the State Immunization Program at 1-800-701-0704 if you have any of these lots.

The Immunization Program will be following up with providers that we identify who have received the recalled lots of these two vaccines. We will be providing additional information in future e-letters regarding replacement of the returned vaccines. Providers identifying these lots in their private vaccine stock should contact their distributor directly.

Dear Doctor Letter from Merck

Voluntary Recall of Certain Lots of
PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)]
and COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and
Hepatitis B (Recombinant) Vaccine] / NDC 0006-4897-00 and 0006-4898-00

December 11, 2007

Dear Customer, Doctor, Healthcare Provider:

Merck & Co., Inc. ("Merck") has initiated a voluntary recall in the United States for ten lots of PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and two lots of COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine]. This letter is being written to inform you of this recall, and to advise you not to administer any vaccine from the vaccine lots being recalled. The lots that are being recalled are:

PRODUCT DESCRIPTION	LOT #	EXP. DATE
PedvaxHIB®	0677U	11 January 2010
PedvaxHIB®	0820U	12 January 2010
PedvaxHIB®	0995U	16 January 2010
PedvaxHIB®	1164U	18 January 2010
PedvaxHIB®	0259U	17 October 2009
PedvaxHIB®	0435U	18 October 2009
PedvaxHIB®	0436U	19 October 2009
PedvaxHIB®	0437U	19 October 2009
PedvaxHIB®	0819U	09 January 2010
PedvaxHIB®	1167U	10 January 2010
COMVAX®	0376U	05 January 2010
COMVAX®	0377U	08 January 2010

The affected doses were distributed starting in April 2007. No other lots of PedvaxHIB® or COMVAX® and no other Merck products are affected by this recall.

The company is taking this voluntary action due to the fact that we cannot assure sterility for these specific vaccine lots. The potential contamination in these specific lots was identified as part of our standard evaluation of our manufacturing processes. In routine testing of the vaccine manufacturing equipment used to produce PedvaxHIB® and COMVAX®, Merck identified an issue that creates the potential for microorganisms to survive the sterilization process. Specifically, during this evaluation, Merck identified the presence of *Bacillus cereus*. Sterility tests of the vaccine lots themselves have not found any contamination. The potential for contamination of any individual vaccine is low, and, if present, the level of contamination would be low. However, because we cannot guarantee the sterility of these specific lots of vaccine, we are conducting this recall.

Based on this information, Merck recommends that you immediately discontinue use of any of the affected lots. If an individual was vaccinated with a vial of PedvaxHIB® or COMVAX® that contained *B. cereus* or other microorganisms, there is a risk that they could develop localized or disseminated infections. By analogy to other *B. cereus* infections, immunocompromised individuals may be at the greatest risk for these infections.

No potency concerns have been identified for these vaccine lots. Individuals who received vaccine from these lots should complete their immunization series with a Haemophilus b conjugate-containing

vaccine not affected by this recall, but do not need to be revaccinated to replace a dose they received from a recalled lot.

Merck is working closely with the Food and Drug Administration and the Centers for Disease Control and Prevention to inform affected customers of this recall action. If you have purchased any of these affected lots directly from Merck, please return the vaccine to us according to the procedure described below; if you did not purchase directly from Merck, please return the vaccine to your distributor. In addition, if you have further distributed these lots of PedvaxHIB® and COMVAX® to other health care providers or offices, please contact them to ensure that all affected product is returned.

In order to ensure an effective recall and return process, it is important that you do the following for product purchased directly from Merck:

1. Please complete the enclosed Business Reply Card and the Packing Slip labeled "Non-VFC Vaccine" including entry of number of vials returned.
2. Mail the postage paid Business Reply Card even if you do not have any of the product identified above to ensure accountability.
3. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

Stericycle, Attn: Merck Returns
2670 Executive Drive, Suite A
Indianapolis, IN 46241

Credit for product will be issued at the price in effect for purchase directly from Merck at the time of purchase.

For any Vaccines for Children (VFC) vaccine from the affected lots, please do the following:

1. Please complete the Business Reply Card and the Packing Slip labeled "VFC Vaccine" including entry of number of vials returned.
2. Mail the postage paid Business Reply Card even if you do not have any of the product identified above to ensure accountability.
3. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

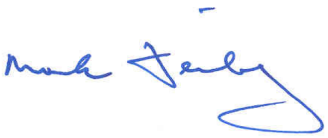
Stericycle, Attn: Merck Returns
2670 Executive Drive, Suite A
Indianapolis, IN 46241

If you have both non-VFC and VFC vaccine to return, you may ship them together in the same shipping container as long as you have accounted for the vials separately using the appropriate forms outlined above.

Please report any potentially vaccine-related adverse experiences to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 (or at www.vaers.hhs.gov), and to Merck at 1-800-672-6372. If you have any questions concerning medical or other issues, please contact the Merck National Service Center at 1-800-672-6372. The Prescribing Information for PedvaxHIB and COMVAX is available from the Merck National Service Center or at www.merckvaccines.com.

We appreciate your immediate attention to this recall and sincerely regret any difficulty caused by this action. Merck is committed to resolving this issue as quickly as possible and to ensure that our full line of vaccines is available to our customers as soon as possible.

Sincerely,



Mark Feinberg, MD, PhD, FACP
Vice President
Medical Affairs and Policy
Merck Vaccines and Infectious Diseases
Merck & Co., Inc.

Hib Vaccine Voluntary Recall Questions and Answers

Voluntary Recall of Certain Lots of *Haemophilus influenza* type b (Hib) Vaccine Produced by Merck & Co., Inc.:
Information for Public Health Agencies and Healthcare Providers

Last month, Merck & Co., Inc. reported that their PedvaxHIB vaccine would be unavailable for shipment pending the results of production quality tests. At that time, Merck expected PedvaxHIB to be available some time in the first quarter of 2008, but reported that the exact timing would be dependent on resolution of a manufacturing issue. On December 13, Merck & Co. will announce that it has initiated a voluntary recall in the United States for certain lots of PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine].

CDC understands that this recall will present several challenges to our public health and provider partners. We are working rapidly to gather and assess information which will allow us to develop guidance for immunization providers and their patients. We will continue to release information as it becomes available.

1. What vaccine is being recalled?
Merck & Co. has initiated a voluntary recall in the United States for ten lots of PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and two lots of COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine]. The affected doses were distributed in the U.S. starting in April 2007.

The lots that are being recalled are:

PRODUCT DESCRIPTION	LOT #	EXP. DATE
PedvaxHIB®	0677U	11 January 2010
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PedvaxHIB®	1167U	10 January 2010
COMVAX®	0376U	05 January 2010
COMVAX®	0377U	08 January 2010

No other lots of PedvaxHIB® or COMVAX® and no other Merck products are affected by this recall.

2. Why are these lots being recalled?
Merck is taking this step as a precautionary measure. The company cannot assure sterility for these specific vaccine lots. The potential contamination in these specific lots was identified as part of Merck's standard evaluation of their manufacturing processes. In routine testing of the vaccine manufacturing equipment used to produce PedvaxHIB® and COMVAX®, Merck identified the presence of a certain bacteria called Bacillus cereus. Sterility tests of the vaccine lots themselves have not found any contamination.

The potential for contamination of any individual vaccine is low, and, if present, the level of contamination would be low. However, because they cannot guarantee the sterility of these specific lots of vaccine, Merck is conducting this recall.

3. What is the extent of the recall?
About 1 million doses of vaccine are being recalled, including ten lots of PedvaxHIB® and two lots of COMVAX® that were distributed in the U.S. as well as vaccine lots within the CDC stockpile.

4. Will children who received vaccine from affected lots need to be revaccinated?
No. Children who received Hib vaccine from affected lots do not need to be revaccinated. No potency concerns have been identified for these vaccine lots.

5. What are the risks to children who received vaccine from affected lots?
Sterility tests of the vaccine lots themselves have not found any contamination. Merck has not received any reports of abscesses or disseminated B. cereus infection in children who received vaccines from affected lots. In addition, no problems have been detected by the Vaccine Adverse Event Reporting System (VAERS) related to the Hib vaccine affected by this recall. However, since sterility of the vaccine cannot be assured, if a child was vaccinated with a vial of PedvaxHIB® or COMVAX® that contained B. cereus or other microorganisms, there may be a risk of developing localized or disseminated infections. Immunocompromised children may be at the greater risk for these infections. These infections are most likely to occur within one week after vaccination.

VAERS will continue to monitor adverse events following vaccination as they are reported. Any potentially vaccine-related adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 (or at www.vaers.hhs.gov), and to Merck at 1-800-672-6372.

6. What should providers do if they have recalled lots in their office?
Providers should immediately discontinue use of any of the affected lots and follow Merck's instructions for returning recalled vaccine (both VFC and non-VFC vaccine).

7. How does this impact the nation's Hib vaccine supply? Are there other Hib vaccine manufacturers?
As a result of this recall, providers who only use Merck Hib vaccines may have none, some or all of their vaccine recalled, and about half of the Hib vaccine in CDC's stockpile is being recalled. CDC realizes that some providers will be faced with the prospect of having children to vaccinate with no vaccine available. There are two U.S. Hib vaccine manufacturers – Merck & Co., Inc. and sanofi pasteur. In the past, each manufacturer has produced about half of the nation's Hib vaccine supply.

8. What is CDC doing in response to the shortage of Hib vaccine?
CDC is in contact with the two U.S. Hib vaccine manufacturers – Merck and sanofi pasteur. CDC is assessing availability of Hib vaccine and timing of future supply, and will make appropriate recommendations soon. Key considerations being addressed by CDC, along with partners such as the American Academy of Pediatrics, the American Academy of Family Physicians, and a representative of CDC's Advisory Committee on Immunization Practices, include whether to change recommendations for Hib vaccine temporarily and how to allocate the smaller CDC stockpile of Merck's Hib vaccines.

9. Will the shortage of Hib vaccine result in an increase in disease occurrence of *Haemophilus influenza* type b?
Fortunately, current immunization rates in the U.S. for Hib vaccine are high. In 2006, about 94% of U.S. children 19-35 months of age were vaccinated against Hib. This has resulted in a dramatic decline in transmission of this bacteria; however, it has not gone away completely. Experience has shown that we cannot let down our guard against vaccine-preventable diseases such as Hib. When immunization rates fall we are susceptible to increases in disease occurrence, so we are taking the current situation very seriously.

10. What should providers tell their patients?
For the time being, providers should continue to use Hib vaccine not affected by this recall according to current ACIP recommendations. If concerned parents contact their providers, they should be informed that children who were vaccinated with vaccine affected by this recall do not need to be revaccinated. Although there have been no reports of any adverse reactions among children who have been vaccinated, parents of children recently vaccinated with recalled vaccine should watch for any signs of infection (such as redness and swelling at the injection site) and contact their providers if such reactions occur. It should be emphasized that sterility tests of

samples from the recalled lots have not found any contamination and the potential of contamination of any individual dose of Hib vaccine is very low.

11. What should providers do if they have no vaccine or little vaccine in their office?
Providers with shortages of vaccine may defer the booster (12-15 month-old) dose of Hib-containing vaccine in fully immunized children who are not otherwise at increased risk of invasive Hib disease (see question 13). Providers who are completely out of Hib vaccine, can contact sanofi pasteur regarding the availability of Hib vaccine to meet immediate short term needs.

12. What should providers do if they have no or little vaccine in their office and they are a VFC provider?
VFC providers should contact their health department. CDC anticipates additional guidance will be available soon.

13. Are some children at high risk for Hib?
Yes. Children at increased risk for Hib include: children with sickle cell disease, leukemia and malignant neoplasms, HIV and certain other immunocompromising conditions, asplenia, as well as American Indian and Alaska Native children. Vaccinating these children according to the recommended schedule is a high priority.